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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

CALIFORNIA RESTAURANT)
ASSOCIATION,)
Plaintiff,)
v.)
THE CITY AND COUNTY OF SAN)
FRANCISCO and THE SAN FRANCISCO)
DEPARTMENT OF PUBLIC HEALTH,)
Defendants.)

Case No. Civ-08-3247 CW

**UNOPPOSED MOTION OF CONGRESSMAN HENRY WAXMAN,
FORMER FDA COMMISSIONER DAVID KESSLER, M.D.,
PUBLIC CITIZEN,
CENTER FOR SCIENCE IN THE PUBLIC INTEREST,
AMERICAN COLLEGE OF PREVENTIVE MEDICINE,
AMERICAN DIABETES ASSOCIATION,
CALIFORNIA CENTER FOR PUBLIC HEALTH ADVOCACY,
TRUST FOR AMERICA'S HEALTH, AND
PROFESSORS OF MEDICINE, NUTRITION, AND PUBLIC HEALTH
FOR LEAVE TO FILE A BRIEF AS AMICI CURIAE**

1 represented California's 30th District since 1974 and is currently the Chairman of
2 the House Committee on Oversight and Government Reform, which has
3 oversight authority over all federal agencies, including the U.S. Food and Drug
4 Administration.

5
6 **David A. Kessler, M.D.**, was appointed Commissioner of the U.S. Food
7 and Drug Administration by President George H.W. Bush in 1990. He was
8 sworn in as Commissioner on the same day that President Bush signed the
9 NLEA into law, oversaw the promulgation of regulations implementing the
10 NLEA, and served as FDA Commissioner through 1997, when he became Dean
11 of the Yale School of Medicine. Dr. Kessler is currently Professor of Pediatrics,
12 Epidemiology, and Biostatistics, at the School of Medicine, University of
13 California, San Francisco. Prior to his tenure at FDA, Dr. Kessler, who is also a
14 lawyer, was a lecturer in food and drug law at Columbia Law School.
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17 **Public Citizen** is a non-profit consumer advocacy organization with a
18 longstanding interest in fighting exaggerated claims of federal preemption of
19 state health and safety regulation and defending consumers' rights to know
20 information that affects their health. Public Citizen's lawyers have argued several
21 significant federal preemption cases before the United States Supreme Court and
22 the lower federal courts, and have also argued several of the seminal cases
23 involving the commercial speech doctrine, including *Virginia State Board of*
24 *Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976), and *Zauderer*
25 *v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985).
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1 **Center for Science in the Public Interest** (CSPI) is a national, non-profit
2 advocacy organization for nutrition and health, food safety, and sound science.
3 CSPI's advocacy was instrumental in getting Congress to consider nutrition
4 labeling legislation in 1989 and in securing passage of the NLEA in 1990, and
5 CSPI has tirelessly advocated for effective FDA enforcement of the NLEA in the
6 seventeen years since its enactment. In addition, CSPI led the advocacy efforts on
7 behalf of the New York City and San Francisco restaurant calorie labeling rules
8 and is working with other cities and states across the nation on similar measures.
9

10 The **American College of Preventive Medicine**, established in 1954, is the
11 national professional society for physicians committed to disease prevention and
12 health promotion. To address the lack of nutrition labeling and the rising obesity
13 rates in adults and children, ACPM introduced the menu-labeling resolution that
14 was passed by the AMA's House of Delegates last year.
15

16 The **American Diabetes Association** is a nationwide non-profit
17 organization founded in 1940 to advance the interests of the now nearly 21
18 million Americans with diabetes. ADA's mission is to prevent and cure diabetes
19 and to improve the lives of all people affected by diabetes. It is the nation's
20 leading voluntary health organization supporting diabetes research, information
21 and advocacy. ADA believes that providing calorie information available
22 through postings on menu boards is a critical step in helping people get the
23 information they need to understand how foods they eat impact their weight and
24 overall nutrition goals.
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1 The **American Public Health Association** is the oldest, largest and most
2 diverse organization of public health professionals in the world and has been
3 working to improve public health since 1872. The Association aims to protect all
4 Americans and their communities from preventable, serious health threats.
5 APHA believes that requiring nutrition labeling at fast-food and other chain
6 restaurants is particularly important given how many of our calories are
7 consumed at restaurants, the large portion sizes and high calorie contents often
8 served at restaurants, and the lack of nutrition information at restaurants.
9

10 **California Center for Public Health Advocacy** is a non-profit
11 organization established in 1999 by California's two public health associations to
12 raise awareness about critical public health issues and is currently the lead
13 supporter of a bill before the California State Legislature to require nutrition
14 labeling on menus and menu boards in chain restaurants.
15
16

17 **Trust for America's Health** is a non-profit, non-partisan organization
18 dedicated to saving lives by protecting the health of every community and
19 working to make disease prevention a national priority.
20

21 **Sharon Akabas, Ph.D.**, is Director of the Masters of Science in Nutrition
22 Program, and Associate Director of the Institute of Human Nutrition, at
23 Columbia University's College of Physicians and Surgeons, where her research
24 focuses on childhood obesity prevention.
25

26 **George L. Blackburn, M.D., Ph.D.**, holds the S. Daniel Abraham Chair in
27 Nutrition Medicine at Harvard Medical School, where his research focuses on
28

1 obesity and clinical nutrition. He is also the Chief of the Nutrition Laboratory
2 and Director of the Center for the Study of Nutrition Medicine at the Beth Israel
3 Deaconess Medical Center, Boston.

4 **Marion Nestle, Ph.D., M.P.H.,** is the Paulette Goddard Professor of
5 Nutrition, Food Studies, and Public Health at New York University, where her
6 research focuses on the role of food marketing as a determinant of dietary choice.
7 Her books include *Food Politics: How the Food Industry Influences Nutrition and*
8 *Health* (2002, revised 2007); and *What to Eat* (2006).

9
10 **Barry M. Popkin, Ph.D.,** is the Carla Steel Chamblee Distinguished
11 Professor of Global Nutrition at the University of North Carolina, Chapel Hill,
12 where he directs the Interdisciplinary Center for Obesity and the Division of
13 Nutrition Epidemiology and studies dynamic changes in diet, physical activity,
14 and body composition, with a focus on rapid changes in obesity.
15
16

17 CONCLUSION

18 For the foregoing reasons, the unopposed motion for leave to file a brief as
19 *amici curiae* should be granted.

20 Respectfully submitted,

21
22 /s/ Monique Olivier
23 Monique Olivier
24 THE STURDEVANT LAW FIRM

25 Deepak Gupta
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27 July 31, 2008

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Date: Sept. 4, 2008

Time: 2:00 p.m.

Place: Courtroom 2, 4th Floor

**BRIEF OF AMICI CURIAE CONGRESSMAN HENRY WAXMAN,
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IN SUPPORT OF DEFENDANTS**

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INTEREST AND IDENTITY OF *AMICI CURIAE*

In requiring fast-food restaurants to disclose calorie information on their menus, the City of San Francisco has stepped into a regulatory gap that Congress intentionally left open to state and local governments when it enacted the Nutrition Labeling and Education Act (NLEA) in 1990. The following *amici curiae* support both San Francisco's decision and its right to make that decision. A more detailed listing of *amici* is set forth in an appendix to this brief.

- U.S. Congressman Henry Waxman, the lead congressional sponsor of the NLEA and currently the Chairman of the committee in the House of Representatives with oversight over FDA;
- David Kessler, M.D., Commissioner of the FDA from 1990 through 1997, the period in which all of the key FDA regulations implementing the NLEA were promulgated;
- Public Citizen, an advocacy organization with longstanding interests in curtailing exaggerated claims of federal preemption of health regulation and defending consumers' right to know information that affects their health;
- Center for Science in the Public Interest, a nutrition advocacy organization and a leading advocate of both the NLEA and state and local menu labeling legislation;
- Leading medical and public health organizations, including the American College of Preventive Medicine, American Diabetes Association, the American Public Health Association, the California Center for Public Health Advocacy, and Trust for American's Health; and
- Distinguished professors and researchers in the fields of medicine, nutrition, and public health, whose names and biographical information are compiled in the appendix.

INTRODUCTION

Two years ago, an important FDA-commissioned report declared that “obesity has become a public health crisis of epidemic proportions.” *The Keystone Forum on Away-from-Home Foods: Opportunities for Preventing Weight Gain and Obesity* (2006), at 1.¹ Echoing the consensus view of the U.S. Surgeon General, the National Academies’ Institute of Medicine, and the American Medical Association, among others, the report concluded that “restaurants should provide consumers with calorie information in a standard format that is easily accessible and easy to use,” allowing consumers to view the information “when standing at a counter, while reviewing a menu board, in a car when reading a drive-through menu, or when sitting down at a table reviewing a menu.” *Id.* at 76, 77-78. The report recognized that “the FDA *does not have regulatory authority* to require nutrition information in restaurants,” but that “state legislatures *do have the authority* to require the provision of nutrition information, and a number of these elected bodies have considered nutrition labeling bills [that] would require calories and/or other nutrition information to be listed on menus or menu boards.” *Id.* at 74 (emphasis added).

In this lawsuit, the fast-food industry repeats arguments that were recently rejected in its challenge to an indistinguishable New York City ordinance. *See N.Y. State Rest. Ass’n v. New York City Bd. of Health*, 2008 WL 1752455 (S.D.N.Y. April 16, 2008), *pending on appeal*, Case No. 08-1892-cv (2d Cir.). Here, as it did there, the industry asks the Court to hold that federal law preempts states and local authorities from doing what the federal government

¹ Available at <http://www.cfsan.fda.gov/~dms/nutrcal.html> (“Keystone Report”); see also FDA Backgrounder, <http://www.cfsan.fda.gov/~lrd/bgowg2.html>.

1 itself lacks authority to do—to hold, in other words, that Congress created a permanent
2 regulatory vacuum on the important issue of mandatory nutrition labeling of restaurant
3 food. Congress did no such thing. To the contrary, Congress focused closely on the issues of
4 preemption and coverage for restaurants during its consideration of the NLEA and enacted
5 carefully limited express preemption provisions that carved out room for state and local
6 government to fill the gaps left by the statute. 21 U.S.C. § 343-1(a)(4); *id.* § 343(q)(5)(A)(i). As
7 the legislation’s chief sponsor in the Senate explained just moments before the final vote:
8 “Because food sold in restaurants is exempt from the nutrition labeling requirements of [the
9 NLEA], the bill does not preempt any State nutrition labeling requirements for restaurants.”
10 136 Cong. Rec. S16607-02, S16608 (Oct. 24, 1990) (Sen. Metzenbaum).
11

12
13 Over the nearly two decades since the NLEA’s enactment, the FDA has consistently
14 taken the same position—most recently in response to the Second Circuit’s request for an
15 *amicus* brief concerning New York’s menu labeling ordinance, which is indistinguishable
16 from San Francisco’s. *See FDA Amicus Brief* (June 16, 2008) (Declaration of Tara Steeley,
17 Exhibit 2); *accord* FDA, *A Guide for Restaurants and Other Retail Establishments* (August 1995),
18 *available at* <http://www.cfsan.fda.gov/~frf/qatext2.html> (“[B]ecause the act exempts
19 restaurant foods that do not bear a claim from mandatory nutrition labeling, State
20 requirements for the nutrition labeling of such foods would not be preempted.”). Indeed,
21 the restaurant industry lobbied the FDA to oppose New York’s menu labeling ordinance as
22 early as April 2007. The FDA, however, concluded that opposition was unwarranted, citing
23 the agency’s “limited authority” concerning restaurants, “the increases in the percentage of
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1 food consumed in away-from home foods, and the general lack of easily accessible nutrition
2 information for these foods.” Letter from R.E. Brackett to D. Garren, dated July 8, 2007.²

3 The Restaurant Association nonetheless contends that San Francisco’s rule is
4 preempted because it is a requirement respecting “claims” of the type regulated in section
5 343(r) of the NLEA. That contention rests on a fundamental misunderstanding of the
6 NLEA’s structure, which is premised on a distinction between requirements that food
7 manufacturers disclose straightforward nutritional information (such as a listing of a total
8 number of calories), on the one hand, and the regulation of descriptive “claims” that
9 industry may choose to make about its food’s nutritional content or health effects, on the
10 other. San Francisco’s rule is unmistakably the former sort of rule: It concerns the
11 mandatory disclosure of purely factual information, not the regulation of descriptive
12 “terms” that restaurants may choose to make “claims” that “characterize” the nutrients in
13 their food.
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17 The Association also maintains that San Francisco’s rule violates the First
18 Amendment. That argument is incompatible with settled law, would turn the commercial
19 speech doctrine upside down, and would jeopardize mandatory disclosure requirements
20 that are ubiquitous in the law—including the very disclosure requirements imposed by
21 section 343(q) of the NLEA. *See Nat’l Elec. Mfrs. Ass’n v. Sorrell*, 272 F.3d 104, 113-16 (2d Cir.
22 2001); *see also Env’tl Def. Ctr. v. E.P.A.*, 344 F.3d 832, 848-51 (9th Cir. 2003).
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25 ² The restaurant industry never informed the New York district court of this
26 correspondence, which was received while the industry’s challenge to the New York rule
27 was still pending before the court. The correspondence was obtained by *amicus* Center for
28 Science in the Public Interest through a Freedom-of-Information-Act request.

BACKGROUND

The NLEA produced groundbreaking changes in the way food is labeled in the United States. It required that basic nutrition facts be disclosed for most foods, prohibited the use of terms that characterize the level of nutrients in a food unless they conform to definitions established by FDA, and required that claims about the relationship between nutrients and health conditions be supported by significant scientific agreement. The Act was introduced in the U.S. House of Representatives by Representative Henry Waxman on July 27, 1989, and signed into law by President George H.W. Bush on November 8, 1990. Although Congress extensively debated a number of issues, including preemption of state law and coverage for restaurants, the basic structure of the legislation—premised on a distinction between the regulation of mandatory nutrition labeling and the regulation of voluntary claims—remained unchanged over the course of the fifteen months during which it was considered.

A. The NLEA's Distinction Between Mandatory Disclosure of Nutrition Information and Voluntary Claims

The NLEA and its regulations “encompass two kinds of information—the mandatory information on nutrients which will appear on the nutrition panel of nearly all food labels [under section 343(q)], and the voluntary information [regulated by section 343(r)] that some manufacturers choose to add to their product labels.” Guarino, *Nutrient Descriptor and Disease Claims for Foods*, 48 Food & Drug L.J. 665, 671 (1993); see also Caswell et al., *The Impact of New Labeling Regulations on the Use of Voluntary Nutrient-Content Claims and Health Claims by Food Manufacturers*, 22 J. Pub. Pol'y & Marketing 147 (2003).

1 The NLEA's differential treatment of mandatory and voluntary statements flows
 2 from Congress's two distinct but complementary purposes—first, “to clarify and to
 3 strengthen the Food and Drug Administration's legal authority to *require* nutrition labeling
 4 on foods,” and second, “to establish the circumstances under which claims *may be made*
 5 about nutrients in foods.” H.R. Rep. No. 538, 101st Cong., 2d Sess. 7 (1990), *reprinted in* 1990
 6 U.S.C.C.A.N. 3336, 3337 (“*House Report*”) (emphasis added). To carry out these twin
 7 purposes, the NLEA added two subsections to the Federal Food, Drug and Cosmetic Act—
 8 section 343(q), which mandates specific, uniform disclosures that must be made on food
 9 labels, and section 343(r), which regulates the descriptive claims that manufacturers may
 10 make about their foods. 21 U.S.C. §§ 343(q), 343(r). The first section governs the mandatory
 11 disclosure of factual nutritional information. The second section creates a framework for
 12 regulation by the FDA concerning when and how food purveyors may voluntarily make
 13 claims using terms that characterize the nutrient levels or health-related effects of their food.
 14 Put another way, the first section (§ 343(q)) tells food manufacturers or vendors what facts
 15 they *must* disclose about their food, while the second section (§ 343(r)) regulates the
 16 descriptive claims they may *choose* to make about their food.

21 **1. Section 343(q): Mandatory Nutrition Labeling.** The nutrition information
 22 labeling provisions of section 343(q) are the heart of the Act. Most American consumers are
 23 familiar with the “Nutrition Facts” panel, a uniform chart that most food manufacturers
 24 must use to list “the total number of calories” in each serving of food, § 343(q)(1)(C), as well
 25 as the amounts of total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary
 26 fiber, sugars, and protein in the food, both as an “amount per serving” and, with the
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exception of sugars and protein, as a percent of a dietary reference value, called the “percent daily value.” § 343(q)(1)(D); *see* 21 C.F.R. § 101.9. As discussed below, restaurant food is not covered by these federal requirements. 21 U.S.C. § 343(q)(5)(A)(i).

2. **Section 343(r): Voluntary Nutrient-Content and Health Claims.** In addition to requiring the disclosure of nutrition information, Congress also responded to the proliferation of dubious, misleading, and confusing claims made by food manufacturers about the nutrition and health effects of their foods. *House Report* at 3337.³ That issue is taken up in the second part of the statute, section 343(r), which distinguishes between two kinds of claims: nutrient content claims (*e.g.* “low salt”) and health-related claims (*e.g.* “fiber reduces the risk of cancer”). §§ 343(r)(1)(A), 343(r)(1)(B).

Prior to the NLEA’s enactment, the FDA had general authority to prohibit false or misleading food advertising or labeling. § 343(a). That authority was sufficient to address a manufacturer’s claims about straightforward factual information, such as information concerning the ingredients or nutrients in a food that was either verifiably true or false. But “an increasing number of food companies had turned to marketing . . . products bearing adjectival descriptors such as ‘lite,’ ‘low,’ ‘reduced,’ or ‘fat free’ because of their perception that such descriptors would lure consumers who thought such terms meant the products were more healthful.” Sims, *The Politics of Fat: Food and Nutrition Policy in America* 202 (1998). In the absence of specific federal standards, these claims were often meaningless or

³ *See generally* Hutt, *A Brief History of FDA Regulation Relating to the Nutrient Content of Food*, in R. Shapiro, ed., *Nutrition Labeling Handbook* 1-27 (1995); Cooper, et al., *History of Health Claims Regulation*, 45 Food Drug Cosm. L.J. 655, 657 (1990); FDA’s *Continuing Failure to Regulate Health Claims for Food: Hearings Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Gov’t Relations*, 101st Cong., 2d Sess. (1989).

misleading. *Id.* The word “light” might mean light in fat, or light in color, or something else entirely. Congress aimed to address this problem by ensuring that such “content claims (such as ‘low salt’ or ‘light’) would have to be consistent with terms defined by the [FDA].” *House Report* at 3337.

Section 343(r) prohibits any “claim” on a food label that expressly or by implication “characterizes” the nutrient level of a food unless “the characterization of the level made in the claim uses terms which are defined in regulations of the [FDA].” § 343(r)(1)(A); § 343(r)(2)(A)(i). “An example of an express claim covered by [§ 343(r)] would be the statement ‘low sodium.’ An example of an implied claim covered by this section would be the statement ‘lite,’ which implies that the product is low in some nutrient (typically calories or fat), but does not say so expressly, or ‘high oat bran,’ which conveys an implied high fiber message.” *House Report* at 3349 (section-by-section analysis). The FDA’s regulations define nutrient content claims for a range of specific descriptive terms including *free, low, high, good source, contains, provides, reduced, less, light or lite, modified, and more.* 21 C.F.R. §§ 101.13, 101.54, 101.56.⁴

With respect to health claims, section 343(r) uses the word “claim” in much the same way, to refer to statements manufacturers choose to make that “characterize” the

⁴ Section 343(r)(1) provides that “[a] statement of the type required by paragraph (q) . . . that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph.” § 343(r)(1). The intent of this sentence was “to make it clear that the information on the nutrition label is not a claim under that provision and therefore is not subject to the disclosure requirements in section 403(r)(2) [343(r)(2)],” although similar statements made outside the nutrition label could be subject to section [343(r)] if they otherwise meet the definition of a “claim.” 136 Cong. Rec. H5836-01, H5841 (July 30, 1990) (Rep. Waxman); *see also* 58 Fed. Reg. 2302, 2303-04 (Jan. 6, 1993); 21 C.F.R. § 101.13(c). Thus, voluntary statements relating to the amount of nutrients in a food can potentially constitute “nutrient content claims” if they implicitly or explicitly “characterize” the amount of the nutrient.

relationship between the nutrients in their foods and diseases or health effects. § 343(r)(1)(B). Health claims, however, are regulated somewhat differently. Instead of providing a list of specific descriptive terms that manufacturers may use, FDA authorizes a health claim only when it determines that there is “significant scientific agreement” that scientific evidence supports the health claim. 21 C.F.R. § 101.14(c).

B. The NLEA’s Exemption of Restaurant Foods from Federal Nutrition Information Disclosure Requirements

The extent to which restaurants should be covered by the NLEA’s nutrition labeling requirements was a matter of considerable debate in Congress. Many of the legislation’s supporters wanted restaurant food to fall under section 343(q)’s mandatory nutrition labeling provisions, but such coverage “was vociferously opposed by the National Restaurant Association,” Sims, *Politics of Fat*, at 200, and was not included in the final legislation. See § 343(q)(5)(A)(i) (exempting food that is “served in restaurants” from the nutrition labeling requirements of section 343(q)).

As a result, the coverage of restaurants turns on the Act’s mandatory-voluntary distinction: As far as federal law is concerned, restaurants are *not* required to provide the kind of nutritional information disclosures—such as listings of the calories or fat in all food items—that is required of packaged foods.⁵ But restaurants are not exempted from the Act’s

⁵ In 2004, the FDA’s Obesity Working Group explained the implications of the regulatory gap left open by section 343(q)’s exemption for restaurant food: “[U]nder the laws administered by FDA, restaurants are not required to provide nutrition information unless a nutrient content or health claim is made for a food or meal. When claims are made, however, the restaurant need only provide information about the amount of the nutrient that is the subject of the claim. Restaurants may, and many do, provide nutrition information on a voluntary basis. Nevertheless, this nutrition information is often in the form of posters, placemats or menu icons, or on the Internet, rather than (continued on next page)

1 regulation of “claims.” So the only circumstance in which the NLEA affects restaurants is
 2 when they choose to make “claims,” within the meaning of section 343(r), that
 3 “characterize” the nutrients or health effects in the foods they serve using certain
 4 descriptive terms—for example, when a restaurant’s menu describes an item as “low fat” or
 5 “heart healthy.” 21 C.F.R. § 101.10; *see* FDA Talk Paper T96-52 (July 30, 1996), *available at*
 6 <http://www.cfsan.fda.gov/~lrd/tpmenus.html> (“This final rule affects only those
 7 restauranteurs who place claims such as ‘low fat’ or ‘heart healthy’ on their menus.”).⁶ A
 8 restaurant that decides to make such a descriptive claim about its food’s nutritional content
 9 is obligated only to disclose “the nutrient amounts that are the basis for the claim.” 21 C.F.R.
 10 § 101.10. Such mandatory quantitative disclosures are considered the “functional
 11 equivalent” of the type of nutritional labeling required of packaged foods by section 343(q).
 12 *Id.*

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19 (footnote continued from previous page)

20 at the point-of-sale. Such information is not always readily available or observable at the point-of-
 21 sale.” FDA, *Calories Count: Report of the Working Group on Obesity* (2004), at Part V.B., *available at*
 22 <http://www.cfsan.fda.gov/~dms/owg-toc.html> (“FDA Calories Count Report”).

23 ⁶ FDA originally decided to exempt restaurant menus—but not restaurant signs, placards or
 24 posters—from its regulations implementing section 343(r). 58 Fed. Reg. 2066 (Jan. 6, 1993). In
 25 response to a lawsuit filed by Public Citizen and Center for Science in the Public Interest, FDA
 26 reversed course just six months later and issued proposed regulations to remove the menu
 27 exemption, 58 Fed. Reg. 33055 (June 15, 1993), but the regulations were rejected by the White House
 28 Office of Management and Budget under pressure from the restaurant industry. *See* Sims, *Politics of Fat*, at 201. The court in that lawsuit ultimately held that the menu exemption was contrary to the NLEA, *Public Citizen v. Shalala*, 932 F. Supp. 13 (D.D.C. 1996), and, about one month later, the agency issued a final rule that adopted its June 1993 proposal. *See* 61 Fed. Reg. 40320 (Aug. 2, 1996) (adopting final rule).

C. The NLEA's Preemption Provisions

The Act's mandatory-voluntary distinction is carried over into its preemption provisions as well. As with restaurant coverage, Congress devoted careful attention to preemption during its consideration of the NLEA. See Sims, *Politics of Fat*, at 199 ("The preemption issue remained a key area of dispute throughout consideration of the food labeling bill, with the basic issue being how far the legislation should go in setting uniform food labeling regulations that preempt state laws.").⁷ In the final moments of the floor debate before the NLEA was formally adopted by the House after its passage in both chambers, Representative Waxman explained that carefully limited federal preemption had been added to the bill to induce industry to support the legislation. 136 Cong. Rec. H12951-02, H12954 (Oct. 26, 1990) ("[I]t was decided that the fairest way to expect the food industry to support a nutrition labeling bill, was to give them *some types of preemption* of some burdensome State laws that interfered with their ability to do business in all 50 States.") (emphasis added). Even Senator Orrin Hatch, who was the leading proponent of stronger federal preemption, conceded that "the carefully crafted uniformity section of this legislation is limited in scope." 136 Cong. Rec. S16607-02, S16611 (Oct. 24, 1990).

In an effort to satisfy industry concerns while remaining "sensitive to the regulatory roles played by the States," the Senate reached a compromise that was "refined to provide national uniformity where it is most necessary, while otherwise preserving State regulatory

⁷ See generally Bradley, *The States' Role in Regulating Food Labeling and Advertising: The Effect of the Nutrition Labeling and Education Act of 1990*, 49 Food & Drug L.J. 649, 659 (1994); Jordan, *Preemption and Uniform Enforcement of Food Marketing Regulations*, 49 Food & Drug L.J. 401, 401 (1994).

1 authority where it is appropriate.” 136 Cong. Rec. S16607-02, S16609 (Oct. 24, 1990) (Sen.
 2 Mitchell); *see also* 136 Cong. Rec. S16607-02, S16611 (Oct. 24, 1990) (Sen Hatch) (“[T]he
 3 compromise makes clear that the national uniformity in food labeling that is set forth in the
 4 legislation has absolutely no effect on preemption of State or local requirements that relate
 5 to such things as warnings about foods or components of food.”). That default position – of
 6 “otherwise preserving State regulatory authority” – is reflected in a special rule of
 7 construction limiting the preemptive effect of the NLEA to only state laws that fall within
 8 the NLEA’s express preemption provisions:

10 The Nutrition Labeling and Education Act of 1990 shall not be construed to
 11 preempt any provision of State law, unless such provision is expressly
 12 preempted under section 403A [21 U.S.C. § 343-1(a)] of the Federal Food,
 Drug, and Cosmetic Act.

13 Pub. L. No. 101-535, § 6(c), 104 Stat. 2535, 2364 (21 U.S.C. § 343-1 note).

14 Because the NLEA exempts restaurant food from its nutrition labeling regime,
 15 Congress specifically considered the question of state and local authority to regulate
 16 nutrition labeling in restaurants. The final legislation contained a preemption provision that
 17 was carefully drafted to preempt any “requirement for nutrition labeling of food that is not
 18 identical to” section 343(q), “*except* a requirement for nutrition labeling of food which is
 19 exempt” from section 343(q)—that is, *except* a requirement for nutrition labeling of
 20 restaurant food. § 343-1(a)(4) (emphasis added). On the day that the NLEA passed the
 21 Senate by a voice vote, the Act’s chief Senate sponsor, Senator Howard Metzenbaum of
 22 Ohio, explained the meaning of this exception:

25 Because food sold in restaurants is exempt from the nutrition labeling
 26 requirements of section 403(q)(1)-(4), *the bill does not preempt any state nutrition*
 27 *labeling requirements for restaurants.*

136 Cong. Rec. S16607-02, S16608 (Oct. 24, 1990) (Sen. Metzenbaum) (emphasis added). The result is an Act that carefully avoids creating a regulatory vacuum: State law is preempted only to the limited extent that federal law specifically covers the same territory.

ARGUMENT

I. The Restaurant Association bears an especially heavy burden to demonstrate “clear and manifest” congressional intent to preempt state and local nutrition disclosure requirements for restaurants.

In its briefing, the California Restaurant Association (CRA) attacks what it describes as three competing “theories” for why menu-labeling ordinances are not preempted by the NLEA, and suggests that the City bears the burden of proving one or more of those “theories.” That is exactly backwards. In fact, the burden is on CRA, and it is an especially heavy one: “Preemption analysis starts with the presumption that the traditional police powers of states are not displaced by federal law unless displacement was the ‘clear and manifest purpose of Congress.’” *Chem. Specialties Mfrs. Ass’n, Inc. v. Allenby*, 958 F.2d 941, 943 (9th Cir. 1992) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). The Ninth Circuit has explained that there are two “practical reasons” for that presumption—first, “Congress has the power to make preemption clear in the first instance,” and second, “if the court erroneously finds preemption, the State can do nothing about it, while if the court errs in the other direction, Congress can correct the problem.” *Id.*

The presumption against preemption is also rooted in an imperative of federalism implicit in the constitutional plan and embodied, among other places, in the Tenth Amendment. An insistence on “clear and manifest” Congressional intent “provides assurance that the ‘federal-state balance’ will not be disturbed unintentionally by Congress or unnecessarily by the courts.” *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (quoting

1 *United States v. Bass*, 404 U.S. 336, 349 (1971)); *see generally* Grey, *Make Congress Speak Clearly*,
 2 77 B.U. L. Rev. 559 (1997); Hoke, *Preemption Pathologies and Civic Republican Values*, 71 B.U. L.
 3 Rev. 685 (1991).⁸

4 San Francisco's regulation "falls squarely within its prerogative to regulate matters of
 5 health and safety, which is a sphere in which the presumption against preemption applies,
 6 indeed, stands at its strongest." *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94 (2d Cir.
 7 2007), *aff'd by an equally divided Court*, 128 S.Ct. 1168 (2008) (discussing preemption in context
 8 of food and drug law); *see Medtronic v. Lohr*, 518 U.S. 470, 485 (1996). Federal courts
 9 presume "that state and local regulation of health and safety matters can constitutionally
 10 coexist with federal regulation" because "the regulation of health and safety matters is
 11 primarily, and historically, a matter of local concern." *Hillsborough County v. Automated Med.*
 12 *Labs., Inc.*, 471 U.S. 707, 719 (1985). "[T]here is indeed no subject of legislation more firmly
 13 identified with local affairs than the regulation of restaurants." *District of Columbia v. John R.*
 14 *Thompson Co.*, 346 U.S. 100, 113 (1953).

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 19 ⁸CRA urges this Court to strike down San Francisco's rule because it regards it as a
 20 novel social science experiment aimed at solving a problem (the obesity epidemic) for which
 21 nobody has found a magic bullet. But, as Justice Brandeis famously observed, one of the
 22 chief virtues of our system of federalism is that "a single courageous State may, if its citizens
 23 choose, serve as a laboratory; and try novel social and economic experiments without risk to
 24 the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932). It is precisely
 25 when "disagreement exists about how best to accomplish [a] goal" that "the theory and
 26 utility of our federalism are revealed, for the States may perform their role as laboratories
 27 for experimentation to devise various solutions where the best solution is far from clear."
 28 *United States v. Lopez*, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring); *see generally* Hills,
Against Preemption: How Federalism Can Improve the National Legislative Process, 82 N.Y.U. L.
 Rev. 1 (2007). The solution San Francisco is pursuing here, moreover, is one that is
 supported by an growing scientific and public policy consensus. *See generally* Wootan Decl.

1 Any analysis of the scope of federal preemption must be guided by the principle that
2 “the purpose of Congress is the ultimate touchstone in every preemption case.” *Lohr*, 518
3 U.S. at 485 (internal quotation marks omitted). That purpose, of course, is discerned
4 primarily “from the language of the pre-emption statute and the statutory framework
5 surrounding it.” *Id.* at 486 (internal quotation marks omitted). In addition, the Court must
6 examine the “structure and purpose of the statute as a whole, as revealed not only in the
7 text, but through the reviewing court’s reasoned understanding of the way in which
8 Congress intended the statute and its surrounding regulatory scheme to affect business,
9 consumers, and the law.” *Id.* (internal citations and quotation marks omitted).

12 Here, the analysis must begin and end with the carefully limited language of the
13 NLEA’s express preemption clause because Congress made clear that “the Nutrition
14 Labeling and Education Act of 1990 shall not be construed to preempt any provision of State
15 law, unless such provision is expressly preempted” by that language. Pub. L. No. 101-535, §
16 6(c), 104 Stat. 2535, 2364 (21 U.S.C. § 343-1 note); see *AT&T Communications of Ill., Inc. v. Ill.*
17 *Bell Tel. Co.*, 349 F.3d 402, 410 (7th Cir. 2003). Thus, the Court’s only task is to determine
18 whether San Francisco City’s rule falls within “‘the domain expressly pre-empted’ by that
19 language.” *Lohr*, 518 U.S. at 484 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)).
20 To the extent that there is any ambiguity—and, as explained below, there is none—this
21 Court has a “duty” to adopt a plausible reading of the statute that preserves local
22 autonomy. See *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (“[I]ndeed, even if its
23 alternative were just as plausible as our reading of that text . . . we would nevertheless have
24 a duty to accept the reading that disfavors pre-emption.”).

1 **II. The NLEA leaves San Francisco free to enact mandatory nutrition information**
 2 **disclosure requirements for restaurant food.**

3 Section 343(q) of the NLEA requires that food purveyors disclose specific nutrition
 4 information about most food products sold in the United States, including “nutrition
 5 information that provides . . . the total number of calories . . . derived from any source . . . in
 6 each serving size or other unit of measure of the food.” § 343(q)(1)(C)(i). Under NLEA’s
 7 preemption provision, states and local governments are *not* free, as a general matter, to
 8 adopt “any requirement for nutrition labeling of food” that is not “identical” to what federal
 9 law requires. § 343-1(a)(4). Thus, San Francisco could not adopt a rule requiring the
 10 disclosure of the amount of calories on the front of cereal boxes sold in San Francisco
 11 grocery stores.
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13 But San Francisco is not similarly restrained when it comes to regulating local
 14 restaurants. As discussed above, Congress sought to avoid a regulatory vacuum by
 15 intentionally excepting state requirements for nutrition labeling of restaurant food from
 16 NLEA preemption at the same time that it exempted restaurant food from the new federal
 17 labeling requirements. The NLEA preempts “any requirement for nutrition labeling of food
 18 that is not identical to the requirement of section 343(q) . . . *except a requirement for nutrition*
 19 *labeling of food which is exempt*” under that section—i.e., a requirement for nutrition labeling
 20 of restaurant food. § 343-1(a)(4) (emphasis added); *see* § 343(q)(5)(A)(i) (providing that
 21 section 343(q)’s nutrition labeling requirements “shall not apply to food . . . which is served
 22 in restaurants or other establishments in which food is served for immediate human
 23 consumption or which is sold for sale or use in such establishments”).
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1 Taken together, these three provisions—sections 343-1(a)(4), 343(q)(5)(A)(i), and
 2 343(q)(1)(C)(i)—demonstrate that Congress intended that the NLEA would not preempt
 3 state requirements “for nutrition labeling” —including labeling “that provides . . . the total
 4 number of calories” —for “food . . . which is served in restaurants.” The NLEA, in other
 5 words, specifically does *not* preempt state-law requirements that restaurants disclose
 6 nutritional facts, such as the calorie content of their food.

8 The FDA has consistently taken a position in keeping with that straightforward
 9 interpretation. In April 2008, the FDA reissued guidelines, reaffirming its view that states
 10 and local governments may “require restaurant foods to bear nutrition labeling even if the
 11 food is exempt under Federal requirements [B]ecause the [NLEA] exempts restaurant
 12 foods that do not bear a claim from mandatory nutrition labeling, State requirements for the
 13 nutrition labeling of such foods would not be preempted.” FDA, *Labeling Guide for*
 14 *Restaurants and Other Retail Establishments Selling Away-From-Home Foods*.⁹ Notably, this
 15 FDA statement specifically distinguishes between “mandatory nutrition labeling” of the
 16 type required under section 343(q) —from which restaurant food is exempt— and “foods that
 17 bear a claim” under section 343(r), and follows the common-sense reading of the statute
 18 discussed above. Moreover, prior and subsequent FDA statements, including its most recent
 19 amicus brief in the Second Circuit, are fully consistent with that analysis. *See, e.g., Keystone*
 20 *Report* at 74; *FDA Calories Count Report* at V.B.

24 CRA’s motion for a preliminary injunction makes no attempt to reconcile its
 25 preemption argument with the savings clause contained in § 343-1(a)(4). As the Supreme
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27 ⁹ Available at <http://www.cfsan.fda.gov/~dms/labrguid.html>

1 Court has explained, “[t]hat Congress added the remainder of the provision is evidence of
2 its intent to draw a distinction between state labeling requirements that are pre-empted and
3 those that are not.” *Bates*, 544 U.S. at 449. Section 343-1(a)(4) distinguishes between
4 “requirement[s] for nutrition labeling of food” that are preempted and those that are not,
5 and specifically places restaurant nutrition-labeling in the latter category. CRA offers no
6 principled basis for distinguishing between the sphere of regulation of nutritional
7 information in restaurants that Congress expressly left open to state and local regulation in
8 section 343-1(a)(4) (the companion preemption provision to section 343(q)), and the types of
9 regulations respecting “claims” within the meaning of sections 343-1(a)(5) (the companion
10 preemption provision to section 343(r)). CRA’s position would thus effectively read the
11 savings-clause out of the statute as far as restaurants are concerned.

14 Not only is there no “clear and manifest” evidence of Congressional intent to
15 preempt restaurant labeling regulations like San Francisco’s, *Lohr*, 518 U.S. at 485, but the
16 clearest evidence of Congressional intent—in the form of statutory language, legislative
17 history, and agency interpretation, all addressing precisely the question of preemption of
18

1 state nutrition labeling requirements for restaurant food—points decisively away from
2 preemption.¹⁰

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4 **III. San Francisco’s ordinance does not regulate voluntary “claims” that use
descriptive “terms” to “characterize” nutrient levels or health effects.**

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6 CRA attempts to sidestep Congress’s decision to save local restaurant nutrition-
7 labeling requirements from preemption by arguing that the San Francisco rule covers the
8 same ground as section 343(r)’s prohibition of unauthorized or unsubstantiated descriptive
9 “claims” that food purveyors choose to make about their food. *See* § 343(r) (prohibiting any
10 “claim” that “characterizes” the nutrient content of food unless the “characterization”
11 employs specific “terms” defined by the FDA); § 343-1(a)(5) (preempting state law
12 “respecting any claim of the type described in section 343(r)”). For this express preemption
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17 ¹⁰CRA obliquely suggests (Mtn. for Prelim. Inj. at 8-9) that San Francisco has somehow
18 interfered with an FDA policy of “flexibility” concerning how restaurants may present nutrition
19 information. But “FDA does not have regulatory authority to require nutrition information in
20 restaurants” in the first place. *Keystone Report* at 74; *see FDA Calories Count Report* at V.B. Because
21 “the FDA has no statutory authority under the NLEA to mandate nutritional disclosure by the fast
22 food industry,” “its reluctance may be explained simply by its lack of authority.” Michael A.
23 McCann, *Economic Efficiency and Consumer Choice Theory in Nutritional Labeling*, 2004 Wis. L. Rev.
24 1161, 1191 n.164 (2004).

25 “There is no federal pre-emption *in vacuo*.” *Puerto Rico Dep’t of Consumer Affairs*, 485 U.S. 495,
26 503 (1988); *see Pelman*, 237 F. Supp. 2d at 525-26 (rejecting McDonald’s argument that Congress’s
27 decision not to impose mandatory nutrition labeling requirements on restaurants preempts state law
28 nutrition labeling requirements for restaurants); *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 65
(2002) (holding that it is “quite wrong” to view the Coast Guard’s decision not to require propeller
guards on motor boats as the “functional equivalent” of a prohibition against state regulation of the
subject matter; the decision was “fully consistent with an intent to preserve state regulatory
authority”); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 289 (1995) (where agency had no standard
either requiring or prohibiting anti-lock brakes, state claim regarding anti-lock brakes was not
preempted). Thus, that FDA has not required nutrition labeling by restaurants in no way precludes
cities and states from doing so.

1 argument to succeed, CRA must demonstrate that San Francisco Ordinance 40-08 is a
2 “requirement respecting any claim of the type described in section 343(r).” § 343-1(a)(5).

3 But San Francisco’s ordinance has nothing to do with such “claims.” The San
4 Francisco rule merely requires restaurants to disclose factual nutritional information. It
5 neither prevents nor limits the ability of restaurants to make voluntary, descriptive claims
6 characterizing the nutrient content or health effects of their food. Restaurants in San
7 Francisco remain just as free as they were in the past to make such descriptive claims, so
8 long as they comply with federal law.
9

10
11 **A. San Francisco’s ordinance has nothing to do with “claims.”**

12 Any construction of the word “claim” in section 343(r) must be informed by the
13 distinction between mandatory factual disclosures and voluntary descriptive statements on
14 which the entire structure of the NLEA is premised. As discussed in Part I above, the
15 NLEA and its regulations “encompass two kinds of information—the mandatory
16 information on nutrients which will appear on the nutrition panel of nearly all food labels,
17 and the voluntary information that some manufacturers choose to add to their product
18 labels.” Guarino, *Nutrient Descriptor and Disease Claims for Foods*, 48 Food & Drug L.J. 665,
19 671 (1993). Both Section 343(q) and San Francisco’s rule address the former sort of
20 information, while section 343(r) addresses the latter.
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22

23 “The difference between requiring certain information on a food label and merely
24 allowing truthful and non-misleading information to appear on the label cannot be
25 understated. Mandatory labels bind all manufacturers of a given product to provide
26 standardized information about their product so that consumers can make essential choices
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1 . . . Voluntary labels, on the other hand, are typically utilized when a manufacturer wishes
2 to distinguish his product from a competing product.” Keane, *The Case of Food Labeling*, 16
3 Transnat’l L. & Contemp. Probs. 291, 295 (2006). The San Francisco rule, similarly, binds all
4 covered restaurants to provide standardized factual information about their products to
5 allow consumers to make informed choices, but neither prohibits nor permits descriptive
6 claims that restaurants choose to make about the benefits of their food over that of their
7 competitors.
8

9 As used in the NLEA, the word “claim” is a term of art that refers to an express or
10 implied statement about a food product’s nutrient content or health effects that is made
11 voluntarily and intentionally by a manufacturer and that may or may not be substantiated;
12 the purpose of the statute is to protect consumers by ensuring that only substantiated, non-
13 confusing statements are made. *See Webster’s Third International Dictionary* 414 (2002)
14 (defining “claim” as “an assertion, statement, or implication (as of value, effectiveness,
15 qualification, eligibility) often made or likely to be suspected of being made without
16 adequate justification.”). Section 343(r) covers a “claim” made on a food label that
17 “characterizes” the level of a nutrient or the relationship of a nutrient to a disease or health-
18 related condition, providing that such claims “may be made only if the characterization of
19 the level made in the claim uses terms which are defined in regulations of the [FDA].” §§
20 343(r)(1), 343(r)(2)(A)(i).
21

22 The same or similar use of the word “claim” appears in various places in the U.S.
23 Code to denote assertions made by the vendors or manufacturers of food or agricultural
24 products, both within the NLEA, *see* 21 U.S.C. § 343(q)(5)(C) (“[T]he requirements of such
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1 subparagraphs shall not apply to such food if the label, labeling, or advertising of such food
2 does not make any *claim* with respect to the nutritional value of such food...”), and
3 elsewhere, *see, e.g.*, 7 U.S.C. § 2105(a) (“false or unwarranted *claims* in behalf of cotton or its
4 products or false or unwarranted statements with respect to the quality, value, or use of any
5 competing product.”); 7 U.S.C.A. § 2617(f)(2) (“no advertising or sales promotion program
6 shall make any reference to private brand names or use false or unwarranted *claims* in
7 behalf of potatoes or their products”) (emphasis added). In these and other instances, the
8 law regulates voluntary advertising claims in contexts where there is some risk that
9 consumers will be deceived by unsubstantiated assertions or confused by the use of
10 ambiguous or misleading terms.
11

12
13 CRA suggests (Mtn. for Prelim. Inj. at 14) that an interpretation of section 343(r) as
14 limited to voluntary statements leads to an “anomalous conflict between state and federal
15 law” because “states or localities could mandate sellers of packaged foods to ‘disclose’ on
16 the front label the number of calories (or any other nutrient).” But there is no such anomaly
17 because, as described above, San Francisco is restrained from taking that step by section
18 343-1(a)(4)—which preempts nutrition-information disclosure requirements as to packaged
19 foods—regardless of how one interprets section 343(r). CRA further posits that a state or
20 city might “‘mandate’ labeling of ‘low sodium’ foods,” perhaps under circumstances that
21 would conflict with FDA regulation. *Id.* at 14. But as to all food, *both* restaurant food *and*
22 packaged food, any problem arising out of that hypothetical scenario would be addressed
23 by section 343(a) of the Food, Drug and Cosmetic Act, which prohibits false or misleading
24 statements. A statement that a food is “low in fat,” when it in fact is not low in fat under the
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1 federal definition of that term, would mislead consumers and would therefore render that
2 food misbranded under section 343(a). Any state law that required a food manufacturer to
3 do something that makes compliance with federal law impossible would be preempted in
4 any event under the doctrine of conflict preemption.

5
6 In fact, it is CRA's reading of the statute that leads to absurd results. CRA effectively
7 reads "claims" so broadly that virtually *any* statement containing nutritional information on
8 restaurant food constitutes a claim. But it is difficult to sensibly read the language of section
9 343(r), or the regulatory scheme that accompanies it, to cover factual nutrition-information
10 disclosures that are mandated by law. An FDA regulation provides that a restaurant that
11 makes a descriptive claim of the type covered by section 343(r) must disclose "the nutrient
12 amounts that are the basis for the claim," which are considered the "functional equivalent"
13 of the type of nutritional information labeling required of packaged foods. 21 C.F.R. §
14 101.10. But under CRA's construction, there would apparently be no difference between the
15 type of claim that triggers that regulation in the first place and the factual disclosure that
16 must accompany the claim as a result.

17
18
19 **B. San Francisco's ordinance has nothing to do with claims that use descriptive**
20 **"terms" to "characterize" nutrient levels or health effects.**

21 Finally, even if it were true that some disclosures compelled by law constituted
22 "claims" under the NLEA, a simple factual disclosure of the number of calories in a food is
23 not a claim that uses descriptive "terms" to "characterize" a nutrient level within the
24 meaning of section 343(r), and thus would not be a "claim of the type described in section
25 343(r)." § 343-1(a)(5).
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Section 343(r) uses the word “characterize” in the sense of “to describe the character or individual quality of,” as in, for example, “He characterized her in a few well-chosen words.” *American Heritage Dictionary of the English Language* (4th ed. 2006); *see also Webster’s Third International Dictionary* 376 (2002) (defining “characterize” as “to describe the essential character or quality of,” as in “characterize a friend in a few words”). Thus, factual statements that do not implicitly or explicitly use “terms” to “characterize” the nutrient content of food are not “claims” of the type described in section 343(r).

The FDA’s regulations define a nutrient content claim as “[a] claim that expressly or implicitly characterizes the level of a nutrient of a type required to be in nutrition labeling under [the regulations implementing 343(q)].” 21 C.F.R. § 101.13(b). The regulations go on to provide an extensive dictionary of “terms” that “characterize” nutrient levels—including *light, lite, high, rich in, excellent source of, good source of, contains, provides, more, fortified, enriched, added, extra, and plus*. 21 C.F.R. §§ 101.54-101.69; *see also FDA, Definitions of Nutrient Content Claims, Food Labeling Guide – Appendix A*, <http://www.cfsan.fda.gov/~dms/flg-6a.html>; *FDA, Label Claims: Nutrient Content Claims*, <http://www.cfsan.fda.gov/~dms/lab-nutr.html>. The FDA has limited section 343(r)’s coverage to any “claim that expressly or implicitly *characterizes* the level of a nutrient,” 21 C.F.R. 101.13(b) (emphasis added), and thus confirms that a statement is a claim within the meaning of section 343(r) only if it uses descriptive terms—such as “low,” “more” or “contains”—to characterize the level of nutrients. *See, e.g.*, 21 C.F.R. 101.54(c) (listing “contains” as a descriptive term and limiting its use).

1 More to the point, and in keeping with the plain meaning of the word “characterize,”
 2 the same regulation makes clear that section 343(r) does not extend to straightforward
 3 listings of calorie amounts that are not accompanied by statements that implicitly
 4 “characterize” the calorie content. “The label or labeling of a product may contain a
 5 statement about the amount or percentage of a nutrient if:”
 6

7 (3) The statement does not in any way implicitly characterize the level of the
 8 nutrient in the food and it is not false or misleading in any respect (e.g., “100
 calories” or “5 grams of fat”), in which case no disclaimer is required.

9 21 C.F.R. § 101.13(i)(3).¹¹ Notably, the regulation uses the bare phrase “100 calories” as an
 10 illustration of a statement about the “amount or percentage of a nutrient” that does *not*
 11 “characterize” a nutrient level. Again using “100 calories” as an example, the FDA
 12 explained the reasoning for the regulation as follows:
 13

14 [B]ased on the comments and its review of the 1990 amendments, FDA finds
 15 that there are some circumstances in which an amount claim cannot be
 16 considered to characterize in any way the level of a nutrient in a food. For
 17 example, the statement “100 calories” or “5 grams of fat” on the principal
 display panel of a food would be a simple statement of amount that, by itself,
 conveys no implied characterization of the level of the nutrient.

18 58 Fed. Reg. 2302-01, 2310 (Jan. 6, 1993).

19 FDA’s guidance concerning its regulations expands on the same point: “Nutrient
 20 content claims describe the level of a nutrient or dietary substance in the product, using
 21 terms such as *free*, *high*, and *low*, or they compare the level of a nutrient in a food to that of
 22 another food, using terms such as *more*, *reduced*, and *lite*. An accurate quantitative statement
 23

24 ¹¹The qualification that a statement may not be “false or misleading in any respect” is a
 25 reference to FDA’s general authority, under section 343(a), to regulate false or misleading food
 26 advertising or labeling. Notably, the NLEA does not list section 343(a) among the provisions of the
 27 statute that preempt state law. See Jordan, *Preemption and Uniform Enforcement*, 49 Food & Drug L.J.
 28 at 402.

(e.g., 200 mg of sodium) that does not ‘characterize’ the nutrient level may be used to describe any amount of a nutrient present.” FDA, *Claims that Can Be Made for Conventional Foods and Dietary Supplements* (2003) (emphasis added), available at <http://www.cfsan.fda.gov/~dms/hclaims.html>; see also Guarino, *Nutrient Descriptor and Disease Claims for Foods*, 48 Food & Drug L.J. at 671 (discussing 21 C.F.R. 101.13(i)(3)).

If further confirmation is needed that straightforward disclosures of quantitative calorie information fall outside the scope of section 343(r), it can be found in FDA enforcement letters, a few of which are attached as an appendix to this brief. In one of the attached letters, FDA responded to a request from *amicus* Center for Science in the Public Interest (CSPI) urging the agency to regulate products bearing the statement “0 *trans* fat.” See Letter to M. Jacobson from B. Schneeman, dated Apr. 14, 2006. The FDA letter noted that CSPI had “refer[red] to these statements (i.e., ‘0g *trans* fat’) as claims” and acknowledged that “there are no approved nutrient content claims for *trans* fat.” *Id.* at 1. Nevertheless, the agency rejected the request on the grounds that such bare factual statements concerning the amount of nutrients are not claims at all:

[T]he label or labeling may contain a factual statement about the amount or percentage of a nutrient in accordance with 21 C.F.R. 101.13(i)(3). The use of this kind of factual statement should not in any way imply that there is a little or a lot of the nutrient in the food and is not false or misleading under section 403(a) of the Act. . . . The use of descriptive words, such as ‘only’ or ‘contains,’ would implicitly characterize the level of the nutrient for which there is no definition. A claim that expressly or implicitly characterizes the level of a nutrient may not be made on the label or labeling foods unless the claim is made in accordance with the regulations (21 C.F.R. 101.13(b)).

The ‘0g trans fat’ statements presented in your letter are considered factual statements, rather than nutrient content claims, in accordance with § 101.13(i)(3) and the products are not considered misbranded under the Act.

Id. at 2 (emphasis added).

1 In short, San Francisco's rule does not come close to addressing "claims" that
2 restaurants may decide to make about their food, let alone claims that "characterize"
3 nutrient levels using descriptive "terms" of the type regulated by section 343(r) and its
4 implementing regulations. Rather, San Francisco's ordinance compels the disclosure of
5 straightforward factual nutrition information for certain restaurant food, just as section
6 343(q) mandates similar disclosures for packaged food, and thus falls squarely into the
7 sphere that Congress intentionally left open to the states.
8

9 **IV. The Restaurant Association's First Amendment theory stands the commercial-**
10 **speech doctrine on its head.**

11 To explain why CRA's First Amendment theory is misguided, it would be difficult
12 for us to improve upon *National Electrical Manufacturers Association v. Sorrell*, 272 F.3d 104,
13 113-16 (2d Cir. 2001), which upheld a Vermont law requiring labeling of mercury-containing
14 lightbulbs, or *Environmental Defense Center v. EPA*, 344 F.3d 832, 848-51 (9th Cir. 2003), which
15 followed *Sorrell* in upholding a federal requirement that storm-sewer providers disclose
16 information concerning environmental hazards. We write only to highlight the breathtaking
17 implications of the Restaurant Association's position.
18

19 Adopting CRA's plea for intermediate or heightened scrutiny would not only run
20 afoul of cases like *Sorrell* and *Environmental Defense*, but would turn the commercial-speech
21 doctrine upside down. In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer*
22 *Council*, 425 U.S. 748 (1976), the first case to establish First Amendment protection for
23 commercial speech, the consumer plaintiffs wanted information about drugs so they could
24 make informed decisions in the marketplace. The Court struck down a statute barring drug-
25 price advertising because the "consumer's interest in the free flow of commercial
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1 information . . . may be as keen, if not keener by far, than his interest in the day's most
 2 urgent political debate." *Id.* at 763.

3 The commercial-speech doctrine that grew out of *Virginia Board* has consistently
 4 observed a "constitutional presumption favoring disclosure over concealment," *Ibanez v. Fla.*
 5 *Dep't. of Bus. and Prof'l Reg.*, 512 U.S. 136, 145 (1994), because "disclosure furthers, rather
 6 than hinders" First Amendment values: "Protection of the robust and free flow of accurate
 7 information is the principal First Amendment justification for protecting commercial
 8 speech." *Sorrell*, 272 F.3d at 114. It is for this reason that commercial disclosure
 9 requirements—including requirements justified by promotion of the public health—are
 10 assessed under the reasonable-relationship test of *Zauderer* rather than the intermediate-
 11 scrutiny standard of *Central Hudson*. *Id.* at 115 (citing *Zauderer v. Office of Disciplinary*
 12 *Counsel*, 471 U.S. 626 (1985); *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S.
 13 557 (1980)); *cf. Rubin v. Coors Brewing Co.*, 514 U.S. 476, 484 (1995) (citing federal nutrition
 14 labeling requirements as evidence of a trend "favor[ing] greater disclosure of information,
 15 rather than less"). But as *Sorrell* recognized, subjecting purely factual commercial disclosure
 16 requirements to heightened scrutiny would upend these settled principles and distort the
 17 commercial speech doctrine into a *barrier* to "the free flow of information" critical to
 18 promoting public health. *Id.* No existing law requires such a topsy-turvy result.

19 CRA's attempts to distinguish *Sorrell*, *Environmental Defense*, and *Zauderer* are
 20 unpersuasive. First, the City ordinance does not "dictate a specific message," *Env't'l Defense*,
 21 344 F.3d at 849, but requires only the disclosure of factual information to consumers. Fast-
 22 food restaurants have every right to disagree with San Francisco about whether disclosing

1 calorie information helps reduce obesity. The expression of that view – whether in CRA’s
2 brief to this Court, or in the public square, or before the City Council – is protected by the
3 First Amendment, and it will continue to be. The City’s regulation does not force CRA to
4 express a contrary view any more than the Vermont law in *Sorrell* forced the lightbulb
5 manufacturers to express the view that mercury is dangerous or the EPA’s regulation in
6 *Environmental Defense* forced storm-sewer providers to express the view that stormwater
7 discharges are hazardous. Second, the proposition that *Zauderer* applies only to disclosure
8 requirements that prevent deception is one that has been explicitly rejected in similar cases.
9
10 *See Sorrell*, 272 F.3d at 115; accord *Pharmaceutical Care Mgmt. Ass’n v. Rowe*, 429 F.3d 294 (1st
11 Cir. 2005). Although the overall goal of the San Francisco ordinance is plainly to reduce
12 obesity, it is analyzed under *Zauderer* because “it is inextricably intertwined with the goal of
13 increasing consumer awareness” of high calorie content in a variety of restaurant foods.
14 *Sorrell*, 272 F.3d at 115. In any event, San Francisco’s rule is in fact designed to prevent
15 consumer deception and confusion concerning calorie content, and so *Sorrell* controls even if
16 one applies the cramped (and incorrect) interpretation that CRA urges.

17
18
19 CRA’s theory in this case is even more radical than the position rejected in *Sorrell* and
20 *Environmental Defense* because it asks the Court to apply not just intermediate scrutiny, but
21 *strict scrutiny*, on the theory that the San Francisco rule constitutes “compelled speech”
22 under *United States v. United Foods, Inc.*, 533 U.S. 405 (2001). To appreciate just how much
23 CRA’s position would disrupt settled law, consider how it would change the outcome in
24 many cases that have adopted *Sorrell*’s approach in the face of compelled-speech challenges
25 to various disclosure and posting laws. *See, e.g., Rowe*, 429 F.3d 294 (1st Cir. 2005)

(upholding Maine law requiring intermediaries between drug companies and pharmacies to disclose conflicts of interest and financial arrangements); *UAW-Labor Employment & Training Corp. v. Chao*, 325 F.3d 360, 365 (D.C. Cir. 2003) (upholding requirement that federal contractors post notices at all of their facilities informing employees of rights under federal labor law that protect employees from being forced to join union or to pay mandatory dues for costs unrelated to representational activities); *United States v. Wenger*, 292 F. Supp. 2d 1296, 1303-04 (D. Utah 2003) (upholding federal securities disclosure requirements); *BellSouth Adver. & Pub. Corp. v. Tenn*, 79 S.W.2d 506, 516-21 (Tenn. 2002) (upholding requirement that “baby Bell” phone company disclose names of its local-phone-company competitors). CRA does not even attempt to grapple with this line of post-*United Foods* cases.

As these cases recognize, “the First Amendment’s guarantee of freedom from ‘compelled speech’ is not absolute. Particularly in the commercial arena, the Constitution permits the State to require speakers to express certain messages without their consent, the most prominent examples being warning and *nutritional information labels*.” *Entertainment Software Ass’n v. Blagovech*, 469 F.3d 641, 651 (7th Cir. 2006) (emphasis added) (distinguishing between “opinion-based” compelled speech and “purely factual disclosures,” such as “whether a particular chemical is within any given product”); *Dutchess/Putnam Rest. & Tavern Ass’n, Inc. v. Putnam County Dep’t of Health*, 178 F. Supp. 2d 396, 406 (S.D.N.Y. 2001) (rejecting “argument that a sign stating that there are health risks to children from secondhand smoke is an ‘ideological message’”); *BellSouth*, 79 S.W.3d at 516-21 (*Zauderer*, not *United Foods*, supplies proper standard in cases involving factual

commercial disclosure requirements); *see also* *Johanns v. Livestock Marketing Ass’n*, 544 U.S. 550, 557 (2005) (explaining that the Court has recognized only two kinds of compelled-speech cases: “true compelled-speech cases,” in which an individual is forced to personally express an opinion with which he disagrees, and “compelled-subsidy cases,” like *United Foods*).

Under CRA’s expansive theory of compelled speech, countless federal, state, and local laws mandating disclosure on a wide range of subjects—from tobacco, pesticides, and pollutants, to hand-washing by restaurant employees—would fall, after being exposed to “searching scrutiny by unelected courts.” *Sorrell*, 272 F.3d at 116. As *Sorrell* noted, even the mandatory nutrition labeling provisions of the NLEA would be among those laws. *Id.* (citing 21 U.S.C. 343(q)). “Such a result is neither wise nor constitutionally required.” *Id.*

CONCLUSION

For the foregoing reasons, the Court should reject the California Restaurant Association’s request to invalidate San Francisco Health Ordinance 40-08.

Respectfully submitted,

/s/ Monique Olivier

Monique Olivier

THE STURDEVANT LAW FIRM

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PUBLIC CITIZEN LITIGATION GROUP

July 31, 2008

Counsel for Amici Curiae

APPENDIX LISTING AMICI CURIAE

This brief is submitted on behalf of the following *amici*:

Congressman Henry Waxman was the chief sponsor of the Nutrition Labeling and Education Act (NLEA) in the U.S. House of Representatives and has long been a leader in Congress on nutrition and food policy issues. He has represented California's 30th District since 1974 and is currently the Chairman of the House Committee on Oversight and Government Reform, which has oversight authority over all federal agencies, including the U.S. Food and Drug Administration.

David A. Kessler, M.D. was appointed Commissioner of the U.S. Food and Drug Administration by President George H.W. Bush in 1990. He was sworn in as Commissioner on the same day that President Bush signed the NLEA into law, oversaw the promulgation of regulations implementing the NLEA, and served as FDA Commissioner through 1997, when he became Dean of the Yale School of Medicine. Dr. Kessler is currently Professor of Pediatrics, Epidemiology, and Biostatistics, at the School of Medicine, University of California, San Francisco. Prior to his tenure at FDA, Dr. Kessler, who is also a lawyer, was a lecturer in food and drug law at Columbia Law School.

Public Citizen is a non-profit consumer advocacy organization with a longstanding interest in fighting exaggerated claims of federal preemption of state health and safety regulation and defending consumers' rights to know information that affects their health. Public Citizen's lawyers have argued several significant federal preemption cases before the United States Supreme Court and the lower federal courts, and have also argued several of the seminal cases involving the commercial speech doctrine, including *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976), and *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985).

Center for Science in the Public Interest (CSPI) is a national, non-profit advocacy organization for nutrition and health, food safety, and sound science. CSPI's advocacy was instrumental in getting Congress to consider nutrition labeling legislation in 1989 and in securing passage of the NLEA in 1990, and CSPI has tirelessly advocated for effective FDA enforcement of the NLEA in the seventeen years since its enactment. In addition, CSPI led the advocacy efforts on behalf of the New York City and San Francisco restaurant calorie labeling rules and is working with other cities and states across the nation on similar measures.

The American College of Preventive Medicine, established in 1954, is the national professional society for physicians committed to disease prevention and health promotion. To address the lack of nutrition labeling and the rising obesity rates in adults and children, ACPM introduced the menu-labeling resolution that was passed by the AMA's House of Delegates last month.

1 The **American Diabetes Association** is a nationwide non-profit organization
2 founded in 1940 to advance the interests of the now nearly 21 million Americans with
3 diabetes. ADA's mission is to prevent and cure diabetes and to improve the lives of all
4 people affected by diabetes. It is the nation's leading voluntary health organization
5 supporting diabetes research, information and advocacy. ADA believes that providing
6 calorie information available through postings on menu boards is a critical step in helping
7 people get the information they need to understand how foods they eat impact their weight
8 and overall nutrition goals.

9 The **American Public Health Association** is the oldest, largest and most diverse
10 organization of public health professionals in the world and has been working to improve
11 public health since 1872. The Association aims to protect all Americans and their
12 communities from preventable, serious health threats. APHA believes that requiring
13 nutrition labeling at fast-food and other chain restaurants is particularly important given
14 how many of our calories are consumed at restaurants, the large portion sizes and high
15 calorie contents often served at restaurants, and the lack of nutrition information at
16 restaurants.

17 The **California Center for Public Health Advocacy** is a non-profit organization
18 established in 1999 by California's two public health associations to raise awareness about
19 critical public health issues and is currently the lead supporter of a bill before the California
20 State Legislature to require nutrition labeling on menus and menu boards in chain
21 restaurants.

22 The **Trust for America's Health** is a non-profit, non-partisan organization dedicated to
23 saving lives by protecting the health of every community and working to make disease
24 prevention a national priority.

25 **Sharon Akabas, Ph.D.**, is Director of the Masters of Science in Nutrition Program,
26 and Associate Director of the Institute of Human Nutrition, at Columbia University's
27 College of Physicians and Surgeons, where her research focuses on childhood obesity
28 prevention.

29 **George L. Blackburn, M.D., Ph.D.**, holds the S. Daniel Abraham Chair in Nutrition
30 Medicine at Harvard Medical School, where his research focuses on obesity and clinical
31 nutrition. He is also the Chief of the Nutrition Laboratory and Director of the Center for the
32 Study of Nutrition Medicine at the Beth Israel Deaconess Medical Center, Boston.

33 **Marion Nestle, Ph.D., M.P.H.**, is the Paulette Goddard Professor of Nutrition, Food
34 Studies, and Public Health at New York University, where her research focuses on the role
35 of food marketing as a determinant of dietary choice. Her books include *Food Politics: How
36 the Food Industry Influences Nutrition and Health* (2002, revised 2007); and *What to Eat* (2006).

37 **Barry M. Popkin, Ph.D.**, is the Carla Steel Chamblee Distinguished Professor of
38 Global Nutrition at the University of North Carolina, Chapel Hill, where he directs the

1 Interdisciplinary Center for Obesity and the Division of Nutrition Epidemiology and studies
2 dynamic changes in diet, physical activity, and body composition, with a focus on rapid
3 changes in obesity.
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APPENDIX OF STATUTORY AND REGULATORY PROVISIONS

21 U.S.C. § 343. Misbranded food.

A food shall be deemed to be misbranded--

21 U.S.C. § 343(q). Nutrition information

(1) Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides--

* * *

(C) the total number of calories--

(i) derived from any source, and

(ii) derived from the total fat,

in each serving size or other unit of measure of the food,

* * *

(5)(A) Subparagraphs (1), (2), (3), and (4) shall not apply to food --

(i) which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments[.]

21 U.S.C. § 343(r). Nutrition levels and health-related claims

(1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication--

(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or

(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

A statement of the type required by paragraph (q) of this section that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

(2)(A) Except as provided in subparagraphs (4)(A)(ii) and (4)(A)(iii) and clauses (A) through (C) of subparagraph (5), a claim described in subparagraph (1)(A)--

(i) may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary[.]

21 U.S.C. §§ 343-1. National uniform nutrition labeling

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce –

* * *

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 343(q)(5)(A) of this title, or

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title, made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

21 U.S.C. § 343-1, note

The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A [21 U.S.C. 343-1(a)] of the Federal Food, Drug, and Cosmetic Act.

21 C.F.R. 101.10. Nutrition labeling of restaurant foods.

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the nutrient amounts that are the basis for the claim (e.g., “low fat, this meal provides less than 10 grams of fat”) may serve as the functional equivalent of complete nutrition information as described in § 101.9. Nutrient levels may be determined by nutrient data bases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.

21 C.F.R. 101.13. Nutrition content claims – General principles

(a) This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements.

(b) A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36 (that is, a nutrient content claim) may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium" or "contains 100 calories."

(2) An implied nutrient content claim is any claim that:

(i) Describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or

(ii) Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat").

* * *

(i) Except as provided in § 101.9 or § 101.36, as applicable, or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

* * *

(3) The statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., "100 calories" or "5 grams of fat"), in which case no disclaimer is required.

21 C.F.R. 101.60. Nutrient content claims for the calorie content of foods.

(a) *General requirements.* A claim about the calorie or sugar content of a food may only be made on the label or in the labeling of a food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13;

(3) The food for which the claim is made is labeled in accordance with § 101.9, § 101.10, or § 101.36, as applicable; and

(4) For dietary supplements, claims regarding calories may not be made on products that meet the criteria in § 101.60(b)(1) or (b)(2) for "calorie free" or "low calorie" claims except when an equivalent amount of a similar dietary supplement (e.g., another protein supplement) that the labeled food resembles and for which it substitutes, normally exceeds the definition for "low calorie" in § 101.60(b)(2).

(b) *Calorie content claims.* (1) The terms "calorie free," "free of calories," "no calories," "zero calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietarily insignificant source of calories" may be used on the label or in the labeling of foods, provided that:

(i) The food contains less than 5 calories per reference amount customarily consumed and per labeled serving.

(ii) As required in § 101.13(e)(2), if the food meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to disclose that calories are not usually present in the food (e.g., "cider vinegar, a calorie free food").

(2) The terms "low calorie," "few calories," "contains a small amount of calories," "low source of calories," or "low in calories" may be used on the label or in labeling

of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i)(A) The food has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons and does not provide more than 40 calories per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and does not provide more than 40 calories per reference amount customarily consumed and, except for sugar substitutes, per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the “as prepared” form).

(ii) If a food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the caloric content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., “celery, a low calorie food”).

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of meal products as defined in § 101.13(l) or main dish products as defined in § 101.13(m), provided that:

(i) The product contains 120 calories or less per 100 g; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the calorie content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which it attaches.

(4) The terms “reduced calorie,” “reduced in calories,” “calorie reduced,” “fewer calories,” “lower calorie,” or “lower in calories” may be used on the label or in the labeling of foods, except as limited by § 101.13(j)(1)(i) and except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent fewer calories per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the calories differ between the two foods are declared in immediate proximity to the most prominent such claim (e.g., reduced calorie cupcakes “33 1/3 percent fewer calories than regular cupcakes”); and

(B) Quantitative information comparing the level of the nutrient per labeled serving size with that of the reference food that it replaces (e.g., “Calorie content has been reduced from 150 to 100 calories per serving.”) is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or labeling of foods if the reference food meets the definition for “low calorie.”

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

- (i) The food contains at least 25 percent fewer calories per 100 g of food than an appropriate reference food as described in § 101.13(j)(1); and
- (ii) As required in § 101.13(j)(2) for relative claims:
 - (A) The identity of the reference food and the percent (or fraction) that the calories differ between the two foods are declared in immediate proximity to the most prominent such claim (e.g., Larry's Reduced Calorie Lasagna, "25 percent fewer calories per oz (or 3 oz) than our regular Lasagna"); and
 - (B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces (e.g., "Calorie content has been reduced from 108 calories per 3 oz to 83 calories per 3 oz.") is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.
- (iii) Claims described in paragraph (b)(5) of this section may not be made on the label or labeling of food if the reference food meets the definition for "low calorie."



January 11, 2007

Dr. Robert E. Brackett
Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Dr. Brackett:

On behalf of the National Restaurant Association (NRA), I am writing to request that the Food and Drug Administration (FDA) take a clear and firm position concerning recent actions taken by the City of New York. As the press has widely reported, the City's Board of Health recently voted to prohibit food service establishments from serving foods that contain trans fat. We believe this action, while well-intentioned, may actually do more harm than good due to the current shortage of healthier oils and the practical limitations on switching over to such oils in the timeframe mandated by the City. This concern is magnified as we look ahead to the many other jurisdictions around the country that also are considering taking such action.

The City's ban requires that all foods containing artificial trans fats no longer be "stored, distributed, held for service, used in preparation of any menu item or served in any food service establishment or by any mobile food unit commissary;" an exception is made only for "food that is being served directly to patrons in a manufacturer's original sealed package." This farreaching ban takes effect in July 2007 with respect to oils, shortenings, and margarines containing trans fat that are used in frying or in spreads and in July 2008 for all other foods. In other words, the restaurant industry has been given 6 months to cease using many trans-fatcontaining foods and 18 months to cease using these foods altogether.

Although the health risks associated with trans fat were the reported motivation for the City's ban, we believe that this attempt to rid a segment of the food industry of a nutrient raises serious and broader public health concerns. Most importantly, we believe the City completely miscalculated the practical effect of this ban. There is logic to the assumption that an immediate ban on trans fat in restaurants could have a benefit to public health, yet in reality, this assumption misses the central key point: What will the trans fat be replaced with? Indeed, the barriers to immediate transition of Og trans fat oils will force restaurants to replace trans fat with equal or even higher levels of saturated fat-such as that found in lard or palm oil.

Ironically, it was this very concern about the ill effects of high levels of saturated fat that drove the food industry to convert to trans fatty acids in the first place. Now, it would be prudent to adopt a public policy strategy that moves the health agenda forward, not backwards. The food

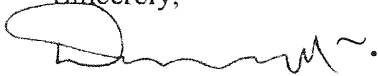
industry has achieved remarkable success in a relatively short period of time in effectively removing or reducing trans fat levels in foods by decreasing the use of partially hydrogenated oils. Several of our members have announced plans to switch to alternative cooking oils, and many such efforts by others are well underway. These efforts require time, technological know-how, and sufficient resources-as well as the availability of healthier oils.

The City, therefore, will unwittingly be ushering in a pronounced rise in the saturated fat levels of the very menu items it targets. This result will not arise ITom indifference, but ITom the lack of options available to restaurants. By focusing narrowly only on the health risks associated with trans fat, the City ignores the practical limitations that further threaten public health.

We appreciate your prompt consideration of this request so that NRA's members are not forced to switch to saturated fat-containing oils and thereby compound the very public health problem the NYC Board of Health was trying to solve. As other localities around the country consider following New York City's lead, we believe that attention must be placed on a broad look at the real public health impact of such trans fat bans.

If you should need additional information or would like to discuss this matter, please contact me.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Donna M. Garren', with a large, stylized initial 'D'.

Donna M. Garren, Ph.D.

Vice President, Health and Safety Regulatory Affairs

cc: Joseph Levitt
Steven Steinborn
Tom Foulkes

1200 SEVENTEENTH STREET NW, WASHINGTON DC 20036-3097 202/331-5900 FAX: 202/331-2429



April 10, 2007

Dr. Robert Brackett
Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Dr. Brackett,

On behalf of the National Restaurant Association, I am writing to request that the Food and Drug Administration take a clear and firm position concerning recent actions taken by the City of New York. As the press has widely reported, the City's Board of Health recently voted to require that restaurants who publicly provide nutrition information post calorie information on menu and menu boards. We believe this action, while well-intended, may actually do more harm than good due to the misleading nature of the Board of Health requirements. This concern is magnified as we look ahead to the many other jurisdictions around the country that also are considering taking such action.

The restaurant industry's objective has always been to provide a wide variety of food options to accommodate the needs of diverse consumers. Americans must be informed over and over again that all foods can be part of a healthy lifestyle and a balanced diet. It is important that the New York City Board of Health examines its role and responsibilities in addressing the public health problem of obesity, with the understanding that our diverse population needs recommendations that are clear and relevant to modern life. Consistent positive messages that promote healthier thinking and lifestyles will always be more successful. The restaurant industry believes it can play a valuable role in serving as a point of dissemination for consumer-focused nutrition information in a meaningful way. Restaurants currently offer a wealth of nutritious options and many provide nutrition information in ways that are more effective than a simple calorie range/count.

We believe that simply posting calorie information on menus and menu boards will not advance the goals underlying the challenges being taken up by the New York City Health Department. This regulation would cover only a very small segment of the entire restaurant industry, severely limiting the program's effectiveness and impact. We believe a program like this will totally miss the mark, and severely limit the effectiveness of a program designed to impact the foods that an estimated 260 million Americans choose.

Restaurants designed around the concept of customers' self-selection of ingredients such as sandwiches may be unable to comply with menu labeling in a non-confusing and accurate way. According to National Restaurant Association research, the make-up of a sandwich consisting of just five items or toppings (such as bread, meat, cheese, lettuce, tomato), can be ordered in 120 different ways. A sandwich comprised of 10 items or toppings could provide 3,628,800 combinations. Furthermore, an individual presented with 15 items for a sub or sandwich has literally billions of possible combinations. As you can see, the possible sandwich combinations of breads, meats, condiments and toppings would make such a labeling scheme completely confusing to consumers and inaccurate for other. More confused consumers should never be the unintended consequence of well meaning ideas to better inform consumers.

The regulation requires that "for menu items that come in different flavors and varieties but are listed as a single menu items (such as beverages, ice cream, pizza or doughnuts), the range of calories for all flavors or varieties of that item shall be listed on menu boards for each size offered for sale."

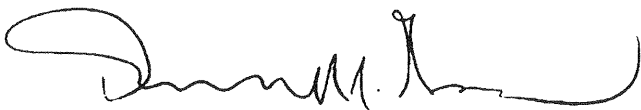
This proposed "solution" will not accomplish the desired goals of the New York City Health Department. It will actually provide a disservice for restaurant guests. We believe that this method is misleading and will only lead to more confusion. Take, for example, a coffee chain. Popular cafes typically offer a very broad variety of options for a coffee drink. A customer can order a cafe latte with skim, 2%, whole, or soy milk. The calorie content of this 16 oz beverage can vary from 160 to 260 calories. That 100 calorie difference means a great deal to someone who is watching his/her caloric intake. Small, specific changes in food and physical activity behaviors can have a positive effect on health. Research shows that affecting energy balance by 100 calories per day could prevent weight gain in most of the population.

A posted calorie range can only lead to more customer confusion and chaos in a restaurant. What happens when a customer wants a 200 calorie latte? Or wants to know what changes affect the total calorie number of a menu item? Are restaurant employees expected to be nutrition experts?

Our industry has been successful because we have listened to our millions of customers and responded to their needs. For those customers who want information, the restaurant chains affected already provide comprehensive nutrition information (more than just calories) in education oriented formats in brochures, tray liners, posters and websites. The regulation (which affects only 10% of NYC restaurants) places unnecessary responsibility on the restaurant chains who already lead the way in providing nutrition information and education on healthy diets to our customers.

We are committed to providing nutritious food choices to our customers. To this end, we have taken substantive steps to encourage the expansion of menus to offer a variety of options. Restaurants have risen to the growing demands of consumers, including great demand for more nutritious foods, fresh ingredients, and fusion of flavors. We appreciate your prompt consideration of this request. If you should need additional information or would like to discuss this matter, please contact me.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Donna M. Garren". The signature is fluid and cursive, with a large initial "D" and a long, sweeping underline.

Donna M. Garren, Ph.D.
Vice President, Health and Safety Regulatory Affairs

cc: Barbara Schneeman
Tom Foulkes



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JUL 8 2007

Donna Garren, Ph.D.
Vice President, Health
and Regulatory Affairs
National Restaurant Association
1200 Seventeenth Street, NW
Washington, DC 20036-3097

Dear Dr. Garren:

This letter responds to your letters dated January 11 and April 10, 2007, to the Food and Drug Administration (FDA or the Agency) on behalf of the National Restaurant Association (NRA). Your letters request that the FDA take a clear and firm position on recent actions by the New York City Health Department to prohibit food service establishments from serving foods that contain *trans* fat (the January 11th letter) and to require that restaurants publicly provide nutrition information regarding calorie information on menu and menu boards (the April 10th letter).

The FDA's *trans* fat labeling final rule (68 FR 41434, July 11, 2003; <http://www.cfsan.fda.gov/~acrobot/ldr03711a.pdf>) requires the gram amount of *trans* fat (without a percent daily value) to be declared on the Nutrition Facts Label. This rule became effective January 1, 2006 for all food under FDA's jurisdiction. As you know, restaurants are not required to provide nutrition labeling unless a nutrient content or health claim is made (21 CFR 101.10).

The Agency is aware of the impact that *trans* fat labeling has on the manufacturer (e.g., reformulation, consumer demand), and of alternative ingredients or processing techniques under development and in use for reducing *trans* fat. FDA has been monitoring industry progress in this effort and will continue to do so. Furthermore, in the *trans* fat final rule (68 FR 41434 at 41488), FDA estimated that it will take three years after the January 2006 effective date (i.e., 2009) to see all the beneficial effects of *trans* fat labeling.

Regarding the January 11th letter, FDA thinks it is prudent to continue to assess the market response and to determine the beneficial effects of *trans* fat labeling before determining additional regulatory options, and FDA thinks it is imprudent to exercise any such action at this time for any state or locality.

Page 2 - Donna Garren, Ph.D.

Regarding the April 10th letter, FDA has limited authority over food served in restaurants, but is aware of the increases in the percentage of food consumed outside the home, the growing percent of calories consumed in away-from-home foods, and the general lack of easily accessible nutrition information for these foods. Although not the only contributing factor to obesity warranting attention, FDA saw the need to enlist the assistance and support of restaurants in addressing the overweight/obesity problem in the United States. Thus, FDA contracted with the Keystone Center to convene a Forum on Away-from-Home Foods. The forum produced a final report: "The Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity," which you can access at: <http://www.cfsan.fda.gov/~dms/nutrcal.html#calcount>. FDA believes that if the report's recommendations are implemented, including restaurants providing consumers with calorie information in an easily accessible standard format, consumers will have a greater variety of healthful food choices available to them and become better informed so that they can make more knowledgeable choices to better manage their weight. For this reason and given FDA's limited authority over food served in restaurants, we do not believe that opposition to the New York City Board of Health requirement is warranted.

We hope this information is helpful.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert E. Brackett", with a stylized flourish at the end.

Robert E. Brackett, Ph.D.
Director
Center for Food Safety
and Applied Nutrition



APR 14 2006

Michael E. Jacobson, Ph.D.
Executive Director
Center for Science in the Public Interest
1875 Connecticut Avenue, NW
Suite 300
Washington, DC 20009-5728

Dear Dr. Jacobson:

This is in response to your letter dated March 14, 2006 to the Food and Drug Administration (FDA). In this letter, you urge the FDA to take prompt action to halt misleading *trans* fat claims on foods that contain significant levels of saturated fat. You state these claims are misleading under section 403(a) and 201(n) of the Federal Food, Drug and Cosmetic Act (the Act). You state that FDA withdrew definitions for nutrient content claims for *trans* fat (68 FR 41434) and simultaneously issued an Advanced Notice of Proposed Rulemaking (ANPRM) to solicit information and data that could be used to establish new nutrient content claims about *trans* fat.

As examples, you list food products that state "0g *trans* fat" (or similar statements) on the principal display panel while the Nutrition Facts panel declares an appreciable amount of saturated fat (i.e., 7g, 11g, 4g, 5g, 6g). You refer to these statements (i.e., "0g *trans* fat") as claims. You further state that consumers expect that a product labeled with these statements to be free of saturated fat.

You are correct that there are no approved nutrient content claims for *trans* fat. As explained in the ANPRM that issued July 11, 2003 (68 FR 41507), the level of scientific evidence does not currently support the establishment of an appropriate reference value for daily consumption of *trans* fat; therefore, FDA withdrew the proposed definitions for *trans* fat free, reduced *trans* fat, and limits on the amount of *trans* fat wherever saturated fat limits are placed on nutrient content claims. The ANPRM, in part, solicited information and data that potentially could be used to establish new nutrient content claims for *trans* fat. FDA supports consumer testing to ensure that any claims about *trans* fat, alone or in combination with other nutrients, such as saturated fat and cholesterol, provides meaningful guidance to consumers and drives the market in a nutritionally beneficial direction. Thus, FDA plans to conduct consumer research in the future to evaluate consumer understanding of "*trans* fat free" and "reduced *trans* fat"

Page 2 - Michael E. Jacobson, Ph.D.

nutrient content claims on product with varying nutritional characteristics (i.e., saturated fat, cholesterol). However, as noted in the ANPRM (at page 41509), if a company wants to make a statement about the fat content of a product that is demonstrably true, balanced, adequately substantiated, and not misleading, FDA would consider the exercise of its enforcement discretion. The FDA has not received any such request or information.

While nutrient content claims for *trans* fat are being considered, the label or labeling may contain a factual statement about the amount or percentage of a nutrient in accordance with 21 CFR 101.13(i)(3). The use of this kind of factual statement should not in any way imply that there is a little or a lot of the nutrient in the food and is not false or misleading under section 403(a) of the Act. For example, "0g *trans* fat" and "2g *trans* fat" are appropriate when, in fact, the Nutrition Facts panel represents the same amount. The use of a percentage is moot since there is no percent Daily Value (%DV) for *trans* fat. The use of descriptive words, such as "only" or "contains," would implicitly characterize the level of the nutrient for which there is no definition. A claim that expressly or implicitly characterizes the level of a nutrient may not be made on the label or in labeling of foods unless the claim is made in accordance with the regulations (21 CFR 101.13(b)). As mentioned above, there are no approved claims for *trans* fat that characterize the level.

The "0g *trans* fat" statements presented in your letter are considered factual statements, rather than nutrient content claims, in accordance with § 101.13(i)(3) and the products are not considered misbranded under the Act. In the future, FDA hopes to develop *trans* fat nutrient content claims based on evolving science and the results of consumer research to provide meaningful guidance to consumers for choosing healthy foods.

Sincerely,

A handwritten signature in black ink, reading "Barbara O. Schneeman". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Barbara O. Schneeman, Ph.D.

Director

Office of Nutritional Products, Labeling
and Dietary Supplements